JAN 2 1 2005

K 041920

# 510(k) Summary
# for
# Infinity Plus Electrotherapy System

## 1. SPONSOR

Empi
599 Cardigan Road
St. Paul, Minnesota 55126-4099

Contact Person: Kathleen Schmitt
Telephone: (651) 415-9000

Date Prepared: July 15, 2004

## 2. DEVICE NAME

| | |
|---|---|
| Proprietary Name: | Infinity Plus Electrotherapy System |
| Common/Usual Name: | Electrical Muscle and Nerve Stimulator |
| Classification Names: | Powered Muscle Stimulator, Interferential Current Stimulator, |

## 3. PREDICATE DEVICES

Empi 300 PV .....K021100

Chattanooga Vectra Pro 4 and Pro 2 Models .....K982324

## 4. INTENDED USE

The Infinity Plus is a multifunction four-channel, multi-waveform electrotherapy device with various treatment modes that allow for neuromuscular electrical stimulation (NMES) and interferential current stimulation (IFS).

As a NMES device, the Infinity Plus device is indicated for the following conditions:

- Retarding or preventing disuse atrophy
- Maintaining or increasing range of motion
- Re-educating muscles

- Relaxation of muscle spasm
- Increasing local blood circulation
- Prevention of venous thrombosis of the calf muscles immediately after surgery

As an IFS device, the Infinity Plus is indicated for the following conditions:

- Symptomatic relief of acute pain
- Symptomatic relief and management of chronic pain
- Adjunctive treatment for post-surgical and post-trauma acute pain

## 5. DEVICE DESCRIPTION

The Empi Infinity Plus Electrotherapy System is a battery-powered/line-powered, multifunction device intended to provide clinicians with the flexibility to prescribe multiple stimulation therapy regimens with the same device. The Infinity Plus offers the following features:

- Channel 1 to 4, which are multi-purpose outputs (IF and NMES)
- High Voltage output dedicated to the High Volt stimulation. (This is named CH5 in the Software Requirements Specification and Software Design Specification. It is a separate channel that is simply the output for the high voltage stimulation).
    - Channel 1, 2, 3 and 4 support stimulation with:
        - IF: 2 independent IF channels using the channel pairs: Channel 1/2 and Channel 3/4
        - PM, NMES, Russian: 4 independent PM channels
        - Serial contractions: 4 dependent channels forming the movement pattern
    - HV out is dedicated to High Volt stimulation
    - All channel outputs are electrically separated from each other
    - Each channel has a dedicated intensity control, with the exception of the HV out. The intensity control of HV is achieved by using the Channel 1 intensity control.

- Maximum stimulation of 100 mA for IF, PM, NMES, and Russian; 500 V for High Volt
- Timed therapy sessions
- Continuous or cycled stimulation
- Adjustable pulse rates
- Adjustable ON and OFF time controls
- Balanced symmetrical biphasic and monophasic high volt waveforms
- Forty-three programs: three conventional interferential, three premodulated interferential, seven High Volt, thirteen NMES, thirteen Russian and four Serial Contraction
- Lock option for clinician to control treatment regimens and stimulus intensity
- Pause function for patient to pause stimulation. During pause, the timer will not count down if timing has been set up. Upon restart, the device assumes the previous treatment stimulation parameters with stimulus intensity of zero

## 6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The Empi Infinity Plus is indicated for use in neuromuscular electrical stimulation, as a High Voltage Stimulation device and for premodulated and conventional interferential stimulation. These are the same four indications as for the Empi 300 PV. The Infinity Plus also incorporates an additional Russian waveform used during NMES. The Chattanooga Vectra Models also incorporates a Russian waveform during NMES stimulation. Therefore, the indications for use of the Infinity Plus are the same as those for predicate electrical stimulator devices that have been previously cleared for marketing in the United States.

As the Infinity Plus is an extension of the Empi 300 PV, they are similar in design and function. Both offer multiple treatment programs, and the user can either choose one or more of these options or customize the treatment regimen within the available parameter ranges. The 300 PV has undergone several changes to result in the Infinity Plus as follows: it is now a four-channel system; it incorporates a Russian Waveform for NMES, and is not indicated for FES or TENS. However, the four channel and the Russian Waveform features are available on the other predicate devices (Vectra Pro Models).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 2005

Empi
C/O Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K041920
Trade/Device Name: Empi Infinity Plus Electrotherapy System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: December 15, 2004
Received: December 16, 2004

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

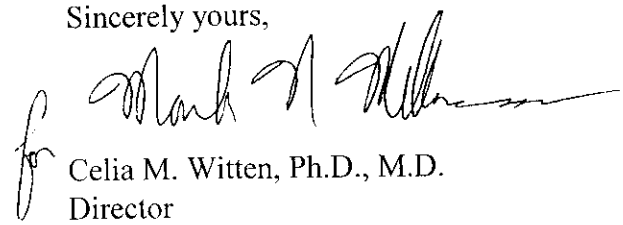
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known):

Device Name: *Infinity Plus Electrotherapy System*

Indications for Use:

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As a NMES device, the Infinity Plus device is indicated for the following conditions:

- Retarding or preventing disuse atrophy
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- Increasing local blood circulation
- Prevention of venous thrombosis of the calf muscles immediately after surgery

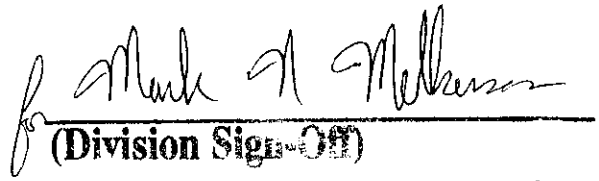
As an IFS device, the Infinity Plus is indicated for the following conditions:

- Symptomatic relief of acute pain
- Symptomatic relief and management of chronic intractable pain
- As an adjunctive treatment for post surgical and post traumatic acute pain

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K041920